UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,145	08/22/2003	Bong Cheol Kim	DE-1501	8727

1109 7590 01/03/2007
ANDERSON, KILL & OLICK, P.C.
1251 AVENUE OF THE AMERICAS
NEW YORK,, NY 10020-1182

EXAMINER	
LAMM, MARINA	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,145	KIM ET AL.	
	Examiner	Art Unit	
	Marina Lamm	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-109* is/are pending in the application.

4a) Of the above claim(s) *73-109* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/06, 11/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the response to the restriction and election of species requirement filed 10/2/06. Claims 38-109 are pending in this application filed 8/22/03, which claims priority to a provisional US application filed 8/23/02. Claims 73-109 have been withdrawn from consideration as directed to non-elected invention. See below.

Election/Restrictions

1. Applicant's election of Group I, Claims 38-72, in the reply filed on 10/2/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicant's election with traverse of species (a) (i.e. administering extract as a pharmaceutical composition, e.g. tablet, powder, capsule, liquid, suspension, granule or syrup) is acknowledged. The traversal is on the ground that species (a) – oral pharmaceutical formulations, (b) – health food additives and (c) – topical cosmetic formulations of Group I "exert the same effect, and therefore, are not patentably distinct." See p. 4 of the reply. This is not found persuasive because the species cannot be used interchangeable, i.e. topical cosmetic compositions cannot be used orally and oral tablets cannot be used topically, etc. However, since the prior art search of species (a) - oral pharmaceutical formulations, did not reveal any relevant prior art references,

the search was extended to the other species. Therefore, both the election of species requirement and the Applicant's traversal are presently moot.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 38-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to treat allergic disease or non-allergic inflammatory disease in a mammal, does not reasonably provide enablement for a method to prevent such diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In *re Wands,* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or unpredictability of the art, (4) the relative skill of those in the art, (5) the breadth of the claims, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) <u>the nature of the invention</u>

The invention is directed to a method for preventing allergic disease or non-allergic inflammatory disease in a mammal comprising administering an extract of hardy kiwifruit to the mammal. Allergic diseases or non-allergic inflammatory diseases of the instant claims include wide variety of conditions. Both oral and topical modes of administration are within the scope of the instant invention.

(2) the state of the prior art

Prior art teaches treating dermatological disorders, including those of inflammatory nature, with fruit extracts, including kiwi fruit extract. See US 6,630,163 issued to Murad, at col. 8, lines 10-29. Further, prior art teaches that kiwifruit possess digestive/laxative properties. See Donaldson, WO 01/70259, of record. Further, kiwifruit extracts might possess an antimutagenic activity according to Lee et al. supplied by the Applicant. However, prior art does not teach *prevention* of allergic diseases or non-allergic inflammatory diseases by oral or topical administration of kiwifruit extract.

(3) the predictability or unpredictability of the art

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to

the question of predictability. See MPEP 2164.03. In this case, the prior art lacks knowledge in regards to the prevention of allergic diseases or non-allergic inflammatory diseases. Thus, the unpredictability of the art is high.

(4) the relative skill of those in the art

The relative skill of the those in the art is high as it requires at least a Master's level of education.

(5) the breadth of the claims

The claim is very broad. It encompasses the prevention of any allergic or non-allergic inflammatory disease regardless of its pathogenesis.

(6) the amount or direction or guidance presented

The instant specification discloses compositions and methods for the *treatment* of allergic or non-allergic inflammatory disease. All the relevant examples in the specification are directed to the treatment of allergic or non-allergic inflammatory conditions. Thus, the specification is enabling for such methods and compositions. The specification does not provide sufficient guidance to allow one skilled in the art to use the claimed composition for the *prevention* of the allergic or non-allergic inflammatory. There is insufficient guidance and objective evidence in the art that would indicate that kiwifruit extract will be able to prevent any allergic or non-allergic inflammatory conditions by either oral or topical route of administration. The fact that kiwifruit extract was demonstrated to possess some anti-allergic and anti-inflammatory properties, is

not an evidence that it will be effective in the prevention of allergic or inflammatory conditions.

(7) the presence or absence of working examples

As stated above, all the examples in the specification are directed to the treatment of allergic or non-allergic inflammatory conditions rather than the claimed prevention. The specification does not provide any working examples that would indicate a composition containing kiwifruit extract is able to prevent an allergic or inflammatory condition.

(8) the quantity of experimentation necessary

The specification provides insufficient guidance with regard to the claimed method and contains no working examples and no evidence which would allow one of skill in the art to predict the efficacy of the claimed method of prevention with a reasonable expectation of success. Moreover, the nature of the invention and the state of prior art have not provided any reasonable expectation of success in the prevention of skin lesion formation. For the above reasons, it appears that one skilled in the art could not practice the invention with the claimed breadth without an undue amount of experimentation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 38, 40, 45-59, 62 and 65-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Murad (US 6,630,163).

Murad teaches a method of treating dermatological disorders, including those of inflammatory nature such as inflammatory dermatoses, with fruit extracts, including kiwi fruit extract. See col. 8, lines 10-29. The fruit extract is present in an amount of 0.01-80 wt. %. See col. 8, lines 13-16. The limitations of Claims 48-50 are inherent in the reference because Murad teaches the same amounts of the extract. With respect to Claims 51-59, these claims are in a product-by-process format and as such as not limited to the extracts produced by a recited method. A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim. See *Scripps Clinic & Research Foundation v. Genentech, Inc.* (CAFC 1991) 927 F2d 1565, 18 PQ2d 1001. Process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985) 771 F2d 695, 227 USPQ 964.

Thus, Murad teaches each and every limitation of Claims 38, 40, 45-59, 62 and 65-67.

Conclusion

7. No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.
Patent Examiner
12/23/06

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER